

#### REMARKS

This paper is filed in response to the official action mailed May 27, 2009 along with a petition for a three months extension of time under 37 CFR 1.136(a) with authorization for the office to deduct the fee or other fees not reasonably anticipated with this reply under 37 CFR 1.17(a)(3) from the applicant Monsanto USPTO deposit account 13-4125. It is respectfully requested that the Examiner enter the amendments to the specification and the claims set forth herein below, and in view of the attendant remarks, find that the claims are now in condition for allowance. It is believed that no new matter is introduced as a result of these amendments.

Claims 1-8, 14, 16-22, 27, 35 and 36 are under examination with this action. With this response, claims 16-17, 22 and 28 have been cancelled and claims 1-8, 14, 18-21, 35-36 are amended and new claim 48 is added. Thus, claims 1-8, 14, 18-21, 27, 35-36 and 48 are pending with this response. A clean copy of the claims is provided at the end of this submission for the convenience of the Examiner. Basis for the amendments to the claims can be found as follows:

Basis for “Bacillus species” can be found throughout the specification in relation to the proteins of the present invention, and particularly in the first full paragraph of the Detailed Description of the Invention bridging pages 13-15. Basis for “amino acid sequence substantially as set forth in SEQ ID NO:6” can be found in the first paragraph of the Summary of the Invention bridging pages 3-4, as well as throughout the specification as filed. Basis for the amendments to claim 6 and other claims with language reflective of “modified sequence intended for use in plants” can be found at least at lines 10-11 in the first full paragraph on page 7; and with reference to SEQ ID NO:6, “amino acid position 44-365” basis can be found at least on page 42 at lines 20-21. Basis for amendments to claim 14, particularly with reference to sequence disclosed in the present application and hybridization under stringent hybridization conditions can be found at least in the paragraphs bridging 14-15 and 20-21. Basis for “toxic” can be found at least at page 21, lines 18-24 as well as throughout the specification as filed. Basis for new claim 48 can be found at least in the paragraph bridging pages 14 – 15 and throughout the specification as filed.

It is believed that the amendments to the claims are fully supported by the specification as filed and that no new matter has been added.

Addressing Each Numbered Paragraph of the Office Action

1. The Examiner has indicated that the traversal of the requirement for restriction and election was not found persuasive, and that the PCT phase reply to this same requirement albeit under a different designation (lack of unity) was not available to the Examiner and not of record in this application. The Applicant herewith submits the Reply to the Written Opinion submitted in the PCT phase of the parent application, which was submitted to the USPTO Receiving Office and addressed to Anne R Kubelik on May 30, 2006. The traversal in the PCT phase included basis for overcoming the objections to the claims based on lack of unity, lack of novelty, and lack of inventive step. The US is a PCT member state, and the patent offices are bound to consider the arguments made in the PCT phase upon entry into the national stage. It is therefore respectfully requested that the Examiner reconsider the finality of the restriction requirement in this matter based on the arguments submitted in the PCT phase.

2. To the extent that the Applicant desires to have the references listed in the bibliography section of the application as filed, a proper IDS will be submitted along with references.

3. The Examiner has indicated that the sole figure originally filed in the PCT application that is the parent to the current application was missing from the 371 submission. The sole drawing consisting of three pages labeled Figure 1A, Figure 1B, and Figure 1C, is submitted along with this paper. The three (3) Figure pages have been marked as Replacement Sheet pages and as Annotated Sheet pages according to the requirements of 37 CFR 1.84(c), and 37 CFR 1.121(d), inserting the sequence identifiers for all the sequences in that figure consistent with the requirement by the Examiner at numbered paragraph 3 on page 4 of the Office Action to which this paper is responsive. It is respectfully requested that the Examiner enter these pages into the specification. No new matter has been added with these annotations.

4. It is believed that the Examiner has intended to indicate that the Applicants reply to the Request for Information mailed 5 August 2008 was fully responsive and that no additional information is required with reference to that Request.

#### Claim Objections

5. It is believed that the objections to formalities in the claims has been addressed by the amendments to the claims. It is respectfully requested that the Examiner acknowledge that these informalities have been properly addressed.

6. It is believed that the amendments to the claims has addressed the Examiner's concern with reference to claims reciting non-elected sequences. It is respectfully requested that the Examiner withdraw this objection.

7. Applicant has amended claim 35 and related claims, and it is believed that the amendments have obviated this objection. It is respectfully requested that the Examiner withdraw this objection.

#### Claim Rejections – 35 USC 112

8. & 9. The Examiner has rejected claims 1-5, 14, and 21-22 under first paragraph of 35 USC 112, asserting that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner has indicated that the full scope of the nucleic acids encoding *Bacillus thuringiensis* toxins are not described because the specification does not describe structural features that distinguish toxins from *B. thuringiensis* from toxins or other proteins from other sources including manmade toxins and proteins. It is believed that the amendments to the recited claims has overcome this rejection.

The Examiner further recites that the full scope of nucleic acids that hybridize to SEQ ID NO:6 and encode insecticidal proteins are not described, stating that the full scope of the genus has not been described and that the specification does not describe the structural features required for insecticidal toxicity or describe structural features that distinguish insecticidal toxins from proteins that are not insecticidal. The amendments to the claims are believed to obviate this rejection.

However, “It is well settled that patent applicants are not required to disclose every species encompassed by their claims...” (In re Vaeck (CAFC 1991) 947 F2d 488, citing In re Angstadt (CCPA 1976) 537 F2d 498). “..there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.” (Ibid, In re Vaeck)

In this case, the application has taught the ordinary skilled worker through through illustrative examples and terminology, how to identify nucleotide sequences from *Bacillus* species that encode proteins that exhibit the properties of the at least five examples that have been set forth in the specification at SEQ ID NO:4, 6, 8, 10 and 33. These proteins are all derived from *Bacillus* species, all are about the same length and amino acid sequence composition, encoded from nucleotide sequences that the skilled art worker would understand would hybridize to each other under stringent hybridization conditions described in the specification in the paragraph bridging pages 20-21 of the international application publication WO05/019414, which is the parent to the instant application containing the same specification and filed as 35 USC 371. All of the steps can be conducted by the skilled art worker using the teaching of the instant specification to find other members within the genus if these exist outside of the illustrative examples of nucleotide sequences described in the instant specification without undue experimentation. The skilled art worker would understand based on the teachings in the specification that a particular nucleotide sequence discovered from a *Bacillus* species using the sequences in the specification as a probe or primer and that encoded a protein having the physical attributes described herein (length, percent identity at amino acid sequence level to the representative members of the genus described, secreted from the *Bacillus* species, having an N terminal sequence that correlates with the ability to be secreted, and insecticidal activity) would be a species member of the genus claimed. Absent the disclosure of the instant specification, the genus would not have been represented in the art earlier than the priority date of this application. Thus, it is believed that sufficient disclosure has been provided through illustrative examples and terminology, guiding the art worker to determine, without undue experimentation, how to identify other member species within the genus and that the genus has been fully described.

The Examiner has also recited that the full scope of nucleic acids encoding toxins with 70% identity to SEQ ID NO:6 or a variant of it are not described, because neither the specification nor the prior art recite any structural features required for toxicity. The Examiner further relies upon a passage from the specification in asserting that the specification teaches that any toxin would be a variant of SEQ ID NO:6. This is traversed. The specification teaches that “amino acid sequences that are substantially equivalent to the amino acid sequences of the present invention are within the scope of variants of SEQ ID NO:6, that these are intended to be biologically functionally equivalent, exhibiting a sequence similarity to the novel peptides of the

present invention, and that these sequences would exhibit the same or similar functional properties as that of the polypeptides disclosed in the specification, including insecticidal toxicity” (Paraphrased from passage cited by Examiner from specification, at page 26, lines 13-40). In this case, the structural features that the Examiner is overlooking and that are fully described by the specification include amino acid sequences that exhibit substantial equivalence to the *amino acid sequence* of SEQ ID NO:6 from amino acid position 44-364, that are secreted from *Bacillus* species, and that exhibit insecticidal activity consistent with that insecticidal activity illustrated by the examples of the specification that teach the insecticidal activity of the TIC 1201 (SEQ ID NO:6). It is believed therefore that the specification fully describes the features of the toxin protein of the present invention including the metes and bounds as now claimed by the amended claims without including all toxins. Thus it is respectfully requested that the Examiner remove this grounds of rejection.

9. & 11. Rejection under 35 USC 112 Second Paragraph

The Examiner has rejected claims 14, 21-22 27 and 35-36 under 35 USC 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as the invention. It is believed that the rejections have been obviated in view of the claims amendments and so it is respectfully requested that the Examiner remove this grounds of rejection.

12. – 14. Rejection Under 35 USC 102(b) or in alternative, 35 USC 103(a)

The Examiner has rejected claims 1, 5, 14, 21 and 22 under 102(b) as anticipated by, or in the alternative under 35 USC 103(a) as obvious over, Brown et al (1994, US Patent No. 5,308,760). It is believed that the amendments to these claims overcomes this rejection and it is respectfully requested that the Examiner remove this grounds of rejection.

15. Rejection under 35 USC 103(a)

The Examiner has rejected claims 1-5, 14, and 21-22 as being unpatentable over Blenk et al (US Patent No. 5,573,766), in view of Donovan et al (1988, Mol Gen Genet, 214:365-372), and further in view of Donovan (US Patent No. 5,024,837). It is respectfully traversed.

The Examiner has asserted that the skilled worker would have been motivated in view of the cited art to clone additional toxins from the strain taught by Donovan. This is not proper because the claims read on SEQ ID NO:6, which is TIC1201, which was not isolated from strain EG2158 even though the instant specification teaches that EG2158 contained at least two different nucleotide sequences encoding proteins that exhibit significant amino acid sequence identity to TIC1201. Furthermore, the cited art teaches parasporal crystal proteins, i.e., toxin proteins from *Bacillus* species that are not secreted but that are produced and crystallized within the spore cell of a particular *Bacillus* species. The present proteins are secreted proteins that exhibit insecticidal properties and no reference cited teaches that the gene encoding the protein of interest would be a protein that is secreted from a *Bacillus* species. Also, the proteins of the cited art are significantly larger in size and substantially are proteins that exhibit lepidopteran activity. Since the proteins of the present invention are secreted, are not parasporal crystal forming structures, are smaller in size than the proteins of the cited art, and do not exhibit lepidopteran activity, the skilled worker would likely not have been motivated to find additional toxins from a strain in which the presently claimed invention does not exist. It is believed that the amendments to the claims along with the remarks herein obviate the 103(a) rejection of the recited claims and so it is respectfully requested that the Examiner remove this grounds of rejection.

If the applicants attorney can be of any assistance to the Examiner in further understanding the scope and content of the subject matter claimed or otherwise, it is respectfully requested that the Examiner contact the undersigned attorney.

Respectfully submitted,

/Timothy K. Ball /

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